

on behalf of any interested person who has submitted a petition, may publish a proposal to issue, amend, or revoke, under this part, a regulation prescribing a common or usual name for a food, pursuant to part 10 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to part 10 of this chapter.

[42 FR 4716, Jan. 25, 1977; 42 FR 10980, Feb. 25, 1977. Redesignated at 42 FR 14091, Mar. 15, 1977, and amended at 42 FR 15675, Mar. 22, 1977; 42 FR 24254, May 13, 1977]

PART 505—INTERPRETIVE STATEMENTS RE: WARNINGS ON ANIMAL DRUGS FOR OVER-THE-COUNTER SALE

Subpart A—Definitions and Interpretations

Sec.

505.3 Warnings on animal drugs intended for administration to diseased animals.

Subpart B—[Reserved]

Subpart C—Voluntary Warning and Caution Statements

505.20 Recommended animal drug warning and caution statements.

AUTHORITY: Secs. 201, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 360b, 371).

SOURCE: 40 FR 13805, Mar. 27, 1975, unless otherwise noted.

Subpart A—Definitions and Interpretations

§505.3 Warnings on animal drugs intended for administration to diseased animals.

None of the warning or caution statements recommended for use in the labeling of drugs intended for administration to diseased animals shall be construed to suggest or imply that any product of a diseased animal is suitable for food use. (See section 402(a)(5) of the act.)

Subpart B—[Reserved]

Subpart C—Voluntary Warning and Caution Statements

§505.20 Recommended animal drug warning and caution statements.

ACETYLAMINONITROTHIAZOLE FOR POULTRY.

Warning— Discontinue use at least 1 week before slaughtering birds for food to eliminate the drug from the food.

AMINONITROTHIAZOLE (2-AMINO-5-NITROTHIAZOLE) FOR POULTRY.

Warning— Discontinue use at least 1 week before slaughtering birds for food to eliminate the drug from the food.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS).

Caution— Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult veterinarian.

ANTHELMINTICS.

Caution— Consult veterinarian before using in severely debilitated animals.

ANTHELMINTICS: PHENOTHIAZINE.

Warning— Do not treat lactating dairy animals.

Caution— Consult veterinarian before using in severely debilitated animals. Individual animals are occasionally sensitive to phenothiazine.

ANTI-HISTAMINICS FOR EXTERNAL USE.

Caution— If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult veterinarian.

ANTISEPTICS FOR EXTERNAL USE.

Caution— In case of deep or puncture wounds or serious burns consult veterinarian. If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Caution— Use only as directed. Avoid contact with the eyes and mucous membranes. Do not apply to large areas of broken skin. Do not use on cats.

CORTISONE, HYDROCORTISONE, PREDNISOLONE AND PREDNISON PREPARATIONS FOR EXTERNAL USE.

Caution— Do not use where infection (pus) is present, since the drug may allow infection to spread. If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

COUNTERIRRITANTS AND RUBEFACIENTS.

Caution— Do not apply to irritated skin or if excessive irritation develops. Avoid getting into eyes or on mucous membranes.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Caution— Use only as directed. Avoid contact with the eyes and mucous membranes. Do not apply to large areas of broken skin. Not recommended for use on cats.

DIARRHEA PREPARATIONS.

Caution— If symptoms persist after using this preparation for 2 or 3 days, consult veterinarian.

DISPENSERS PRESSURIZED BY GASEOUS PROPELLANT FOR DRUGS FOR EXTERNAL USE.

Caution— Keep away from eyes or other mucous membranes. Avoid inhaling.

This warning is not necessary for preparations especially designed for use on mucous membranes.

Warning— Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

DRESSINGS, PROTECTIVE SPRAY-ON TYPE.

Caution— In case of deep or puncture wounds or serious burns or if redness, irritation, or swelling persists or increases, consult veterinarian.

Keep away from eyes or other mucous membranes. Avoid inhaling.

See also Dispensers Pressurized by Gaseous Propellant * * * for additional

warnings to be included for products under pressure.

ESTROGEN PELLETS IN CATTLE AND SHEEP.

Warning— Implant pellets in _____ (name of the anatomical area) only. Any other location may result in violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

NICARBAZIN FOR POULTRY.

Warning— Do not feed to laying hens in production. Discontinue use at least 4 days before slaughtering birds for food to eliminate the drug from the food.

OPHTHALMIC PREPARATIONS.

Caution— If condition persists or increases discontinue use and consult veterinarian. Keep container tightly closed.

Solutions should also include the following statement: "Do not touch applicator tip to any surface, since this may contaminate solution."

SALMONELLOSIS TREATMENTS FOR POULTRY.

Important— Poultry that have survived salmonella outbreaks should not be kept for laying-house replacements or breeders, unless tests show that they are not carriers.

SULFONAMIDE PREPARATIONS (SYSTEMIC).

Caution— If symptoms persist after using this preparation for 2 or 3 days, consult veterinarian.

SULFONAMIDES FOR EXTERNAL USE.

Caution— If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

If the preparation has not been sterilized, the following statement should also be used.

Caution— This preparation has not been sterilized. Do not use in body cavities or deep wounds.

[40 FR 13805, Mar. 27, 1975, as amended at 47 FR 51563, Nov. 14, 1982]

**PART 507—THERMALLY PROCESSED
LOW-ACID FOODS PACKAGED
IN HERMETICALLY SEALED CON-
TAINERS**

Subpart A—General Provisions

Sec.

507.3 Definitions.

507.5 Current good manufacturing practice.

507.10 Personnel.

Subpart B—[Reserved]

Subpart C—Equipment

507.40 Equipment and procedures.

**Subpart D—Control of Components, Food
Product Containers, Closures, and In-
Process Materials**

507.60 Containers.

**Subpart E—Production and Process
Controls**

507.81 Product preparation.

507.83 Establishing scheduled processes.

507.87 Operations in the thermal processing room.

507.89 Deviations in processing, venting, or control of critical factors.

Subpart F—Records and Reports

507.100 Processing and production records.

AUTHORITY: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

SOURCE: 44 FR 48598, Aug. 17, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 507.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Aseptic processing and packaging* means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) *Bleeders* mean openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders

may serve as a means of removing condensate.

(c) *Come-up-time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) *Commercial processor* includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(e) *Commercial sterility*. (1) “Commercial sterility” of thermally processed food means the condition achieved—

(i) By the application of heat which renders the food free of—

(a) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(b) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(2) “Commercial sterility” of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) *Critical factor* means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) *Flame sterilizer* means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A